

measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63007, Dec. 7, 1994]

§ 872.1720 Pulp tester.

(a) *Identification*. A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.

(b) *Classification*. Class II.

§ 872.1730 Electrode gel for pulp testers.

(a) *Identification*. An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989]

§ 872.1740 Caries detection device.

(a) *Identification*. The caries detection device is a device intended to show the existence of decay in a patient's tooth by use of electrical current.

(b) *Classification*. Class II.

§ 872.1800 Extraoral source x-ray system.

(a) *Identification*. An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification*. Class II.

§ 872.1810 Intraoral source x-ray system.

(a) *Identification*. An intraoral source x-ray system is an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification*. Class II.

§ 872.1820 Dental x-ray exposure alignment device.

(a) *Identification*. A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

§ 872.1830 Cephalometer.

(a) *Identification*. A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental x-rays.

(b) *Classification*. Class II.

§ 872.1840 Dental x-ray position indicating device.

(a) *Identification*. A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996]